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ORIGINAL ARTICLE

Shield kyphoplasty through a unipedicular approach compared to vertebroplasty and balloon kyphoplasty in osteoporotic thoracolumbar fracture: A prospective randomized study

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KEYWORDS

Shield kyphoplasty;
Vertebroplasty;
Balloon kyphoplasty;
Outcome

Summary

Objective: Currently, there are no clinical studies comparing different cement augmentation methods, and no clinical observational studies of a unipedicular approach.

Design, patients, interventions, main outcome measurements: The present study compared three commercially available vertebral augmentation systems: balloon kyphoplasty, vertebroplasty and shield kyphoplasty. The primary objective was to assess change in subjective severity of backache on a visual analog scale (VAS) and subjective improvement in quality of life on the Oswestry Disability Index (ODI), at a mean 6 months post-surgery. The secondary objective was to analyze current radiological imaging (X-ray, and in some cases CT) with regard to height restoration, cement distribution and leakage and recurrent fracture.

Results: Mean follow-up was 5.8 months. Mean preoperative Beck vertebral height index did not significantly differ between the three augmentation system groups ($P > 0.05$). Comparing surgery time, fluoroscopy time and dose-area-product ($\text{cGy} \times \text{cm}^2$) showed a statistically significant difference ($P < 0.01$) in favor of the vertebroplasty technique. Augmentation provided significant improvement in VAS pain assessment, but with no significant difference between augmentation systems. Results on the ODI were less pronounced, with significant improvement of 22% to 45%, but again without significant difference between augmentation systems.

Conclusions: Overall, apart from mostly asymptomatic cement leakage, vertebroplasty could be considered as the surgical procedure of choice.

Level of evidence II: Low-powered prospective randomized trial.

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Introduction

There are hundreds of published studies and case reports on clinical outcome after vertebroplasty and kyphoplasty; most, however, had no control group and therefore did not satisfy the criteria of evidence-based medicine. Nearly all authors described considerable improvement after surgery, and “success rates” of more than 90% is regularly claimed for both vertebroplasty and kyphoplasty.

The current standard techniques of kyphoplasty and vertebroplasty comprise a bipedicular approach to the vertebral body under transillumination. In recent months, a new modified method has become available: the shield kyphoplasty system (Soteira Inc.). For shield kyphoplasty in particular, but also for vertebroplasty, recent biomechanical studies [1,2] described a unipedicular approach to the vertebral body. However, no published clinical studies have compared the different methods, nor are there any clinical observational studies of the unipedicular approach.

The hypothesis to be tested is that the unipedicular approach to the vertebral body can achieve clinical results similar to those of a bipedicular technique. The present analysis compared clinical results with three commercially available vertebral augmentation systems (balloon kyphoplasty, vertebroplasty and shield kyphoplasty), and respective surgery and fluoroscopy times.

Patients and methods

Inclusion and exclusion criteria

The study included patients with osteoporosis proven on DXA scan, and fresh painful single-level osteoporosis with sintering fractures in the middle and lower thoracic spine (TS) and lumbar spine (LS) (Table 1). Symptoms of pain that had arisen within the previous 6 weeks and magnetic resonance tomographic evidence of edema in the affected vertebral body were defined as indicating fresh vertebral body fractures. In all patients, conservative therapies (analgesics according to the WHO scheme, physiotherapy, physical therapy, orthotics adjustment) had proved ineffective for at least 4 weeks. Vertebral augmentation was indicated if levels of provoked percussion pain in the spinous process and of radiologically proven compression fracture agreed.

Patients were excluded if they had no painful vertebral deformation or had considerable degenerative damage,

vertebral deformation (e.g., vertebra plana), tumor and metastasis, local or systemic infection or untreated clotting disorder.

All patients were informed in detail about the central vertebral augmentation technique but were blind to the particular method in their own case. During the information session, the patients agreed to surgery and signed an informed consent form for participation in the study.

Study design

The 66 prospectively included patients were distributed quasi-randomly into three groups: group A, $n=22$, balloon kyphoplasty (Medtronic); group B, $n=22$, vertebroplasty (Stryker); group C, $n=22$, shield kyphoplasty (Soteira).

Follow-up and research parameters

The main hypothesis being tested was that the unipedicular approach to the vertebral body gives similar clinical results to the bipedicular technique. In addition, surgery and fluoroscopy times were documented. Three commercially available vertebral augmentation systems - balloon kyphoplasty (Medtronic), vertebroplasty (Stryker) and shield kyphoplasty (Soteira) - were compared. Radiological analysis comprised plain AP and lateral radiographs: pre-, directly post- and 6 months post-surgery [3].

All patients received a daily standard dose of oral aminobisphosphonate, 1000 mg calcium and 1000 IU vitamin D3. Additionally, physiotherapy and pain medication as required were prescribed. There were no significant differences in baseline characteristics or the planned vertebral levels between the balloon kyphoplasty, vertebroplasty and shield kyphoplasty groups at entry into the study.

Clinical results were assessed on ODI and VAS pre- and 6 months post-surgery.

Surgery

Vertebroplasty

Vertebroplasty was performed through a unipedicular transpedicular approach with one 13-gauge bone biopsy needle (Stryker) placed in the anterior third of the vertebral body. Once the needle was in place, liquid and powder polymethylmethacrylate (high viscosity SpinePlex™, Stryker, Germany) were mixed to toothpaste consistency. Under

Table 1 Patient characteristics.

	Kyphoplasty	Vertebroplasty	Shield kyphoplasty
Number	20	21	18
Age (mean)	63.3 years (range: 53–77)	71.3 years (range: 63–77)	67.1 years (range: 47–79)
Gender (f/m)	14/6	12/8	14/4
Prevalent fractures	1.25 (range: 1–3)	1	1.14 (range: 1–2)
N° single-level	20	21	18
N° thoracic (T9–T12)	4	7	2
N° lumbar (L1–L5)	16	14	16
Cement type	PMMA (high viscosity)	PMMA (high viscosity)	PMMA (high viscosity)



Figure 1 a) lateral radiograph with device filled by cement; b) exemplary presentation of the device (Shield kyphoplasty, Soteira, Berlin-Deutschland).

biplane fluoroscopic guidance, the cement was injected through the needle until the vertebral body was filled in the posterior 25% or until there was leakage. No postural maneuver was performed to retain alignment before or during the procedure. The mean quantity of cement was 3.1 mL (range: 2–4 mL).

Balloon kyphoplasty

Balloon kyphoplasty was also performed through a unipedicular approach with a unilateral working cannula and standard kyphoplasty equipment (high viscosity KyphX HV-R™, Medtronic, Germany). A drill passing through the cannula created a tract for the 20-mm balloon to be inserted into the center of the vertebral body. Cement, mixed according to the manufacturer's recommendations, was injected as described for vertebroplasty. Injection was usually about 14 min after start of mixing. The mean quantity of cement was 3.9 mL (range: 3–5 mL).

Shield kyphoplasty

The Soteira shield kyphoplasty system is a percutaneous minimally invasive system that enables a fractured vertebral body to be accessed through a unipedicular approach. The implant site was prepared by manually creating a cavity, and bone cement (Soteira, high viscosity) was delivered via an implantable cement director, the Shield™ Implant. This is a hollow, self-expandable coated implant that is marketed in a range of sizes and is attached to a disposable delivery system (Fig. 1). The mean quantity of cement was 4.6 mL (range: 3–6 mL).

All vertebroplasty and kyphoplasty procedures were performed by the same surgeon (S.E.), under biplane fluoroscopy and general anesthesia. All patients were discharged around 2 days after surgery.

Post-surgical imaging/control

In all cases, post-surgical AP and lateral radiographs (directly postoperative, 6 months postoperative) were taken to document cement location, check for any possible leakage, prepare a record of the vertebral body, and check for new fractures. Control CT was carried out on patients showing leakage on plain X-ray. The images were analyzed by the author as well as by a radiologist. The Beck index was measured pre- and postoperatively as secondary outcome.

New vertebral fracture of the thoracic and lumbar spine in previously unfractured and pre-fractured vertebrae was defined by at least 20% height reduction.

Ethical board statement

The ethical board of the university of Münster, Germany approved the study (AZ 2010-218-f-s).

Statistical analysis

Data were analyzed using SPSS software (version 10.0; SPSS, Chicago, IL). Dichotomous variables were compared using Fisher's exact and chi square tests. Student's *t*-test was used to compare independent variables. The threshold for statistical significance was $P < 0.05$.

Results

Two of the 66 patients were deceased at the time of the follow-up, and five refused to participate. Therefore, 59 patients completed the questionnaires both pre- and post-operatively and were included in the final follow-up. This resulted in an overall follow-up rate of 89%.

Mean age at surgery was 68 years (range: 53–78 years), and final follow-up was performed at a mean 5.8 months (range: 4–7 months) by an orthopedic surgeon not involved in the primary surgery. At this 6-month follow-up, patients showed significant improvements in VAS and ODI scores compared with preoperative values. Patient characteristics of the three subgroups are given in Table 1:

- group 1 (balloon kyphoplasty): mean VAS score was 90 (SD: 7.07) pre-surgery and 36.5 (SD: 6.36) post-surgery. Mean Oswestry index was 77 (SD: 4.2) pre-surgery and 43.1 (SD: 19.5) post-surgery, an improvement of 45%;
- group 2 (vertebroplasty): mean VAS score was 78.2 (SD: 9.36) pre-surgery and 32.4 (SD: 14.04) post-surgery. Mean Oswestry index was 68.2 (SD: 5.7) pre-surgery and 53.1 (SD: 8.5) post-surgery, an improvement of 22%;
- group 3 (shield kyphoplasty): mean VAS score was 88.16 (SD: 15.06) pre-surgery and 40.16 (SD: 7.44) post-surgery. Mean Oswestry index was 75.7 (SD: 9.1) pre-surgically and 56.1 (SD: 7.6) post-surgically, an improvement of 24%.

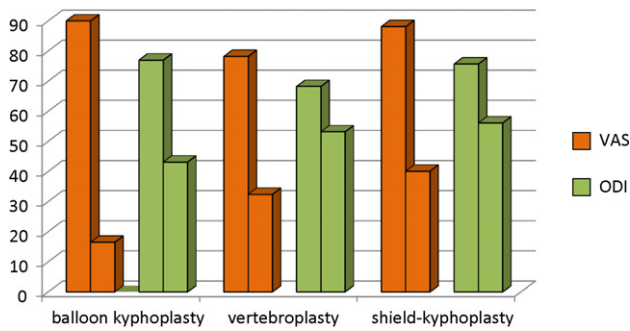


Figure 2 Charts of Oswestry Disability Index and visual analog scale, preoperatively and at final 6-month follow-up.

The mean preoperative Beck index did not differ significantly between groups ($P > 0.05$). Vertebroplasty, balloon kyphoplasty and shield kyphoplasty did not improve vertebral body height, notably in the anterior and central portions ($P < 0.05$) (Table 2).

Comparing surgery and fluoroscopy times and dose-area-product ($\text{cGy} \times \text{cm}^2$) showed a statistically significant difference ($P < 0.01$) in favor of vertebroplasty. Balloon and shield kyphoplasty were comparable, with no statistically significant difference ($P > 0.05$). No clinically relevant complications (e.g., cement leakage into the canal) were observed in any of the three groups. For vertebroplasty, there were four lateral leakages and four in the disk; for balloon kyphoplasty, three laterals and one anterior; and for shield kyphoplasty, one in the disk. These differences between groups were not significant ($P > 0.05$).

No adjacent fractures were observed in the three groups over the period to final follow-up at 6 months (Figs. 2 and 3).

Discussion

This study compared vertebroplasty, balloon kyphoplasty and shield kyphoplasty performed through a unipedicular transpedicular approach by the same surgeon in three similar groups of patients.

The recent standard procedure of central augmentation consists in a bipedicular approach to the vertebral body under transillumination. Recent biomechanical studies [1,2] have described a unipedicular approach.

The theoretical benefits of a unilateral approach are a reduction of up to 50% in the risk associated with cannulating both pedicles, with concomitant reductions in operative time, radiation exposure and costs [4]. Biomechanical testing showed that experimental unilateral kyphoplasty had properties comparable to bipedicular kyphoplasty. Steinmann et al. [4] demonstrated in a cadaveric study that unipedicular kyphoplasty was comparable to bipedicular kyphoplasty in restoring vertebral strength, stiffness and height. They also were able to show that the unipedicular approach entailed no greater risk of lateral wedging.

A randomized clinical study comparing the results of different cement augmentation systems performed through a unipedicular transpedicular approach was therefore performed (Table 3).

The primary objective was to assess change in subjective VAS estimation of backache and subjective improvement in

Table 2 Radiographic outcome, surgery time and fluoroscopy time.

Technique	Time of surgery (mean)	Dose-area product ($\text{cGy} \times \text{cm}^2$)	Fluoroscopy time (mean)	Preoperative Beck index (mean)	6-months Beck index (mean)
Kyphoplasty ($n = 20$)	26 min (range: 19–36)	1595,78 (range: 980,2–2202,68)	1,92 (range: 1,4–2,4)	0,84 (range: 0,7–1)	0,83 (range: 0,7–1)
Vertebroplasty ($n = 21$)	18.4 min (range: 14–29)	837 (range: 132,91–1634,2)	1,1 (range: 0,3–1,5)	0,85 (range: 0,66–0,96)	0,85 (range: 0,67–0,97)
Shield kyphoplasty ($n = 18$)	31.14 min (range: 18–50)	1617,58 (range: 562,8–2503,87)	1,55 (range: 0,9–2,4)	0,85 (range: 0,66–1)	0,85 (range: 0,66–1)

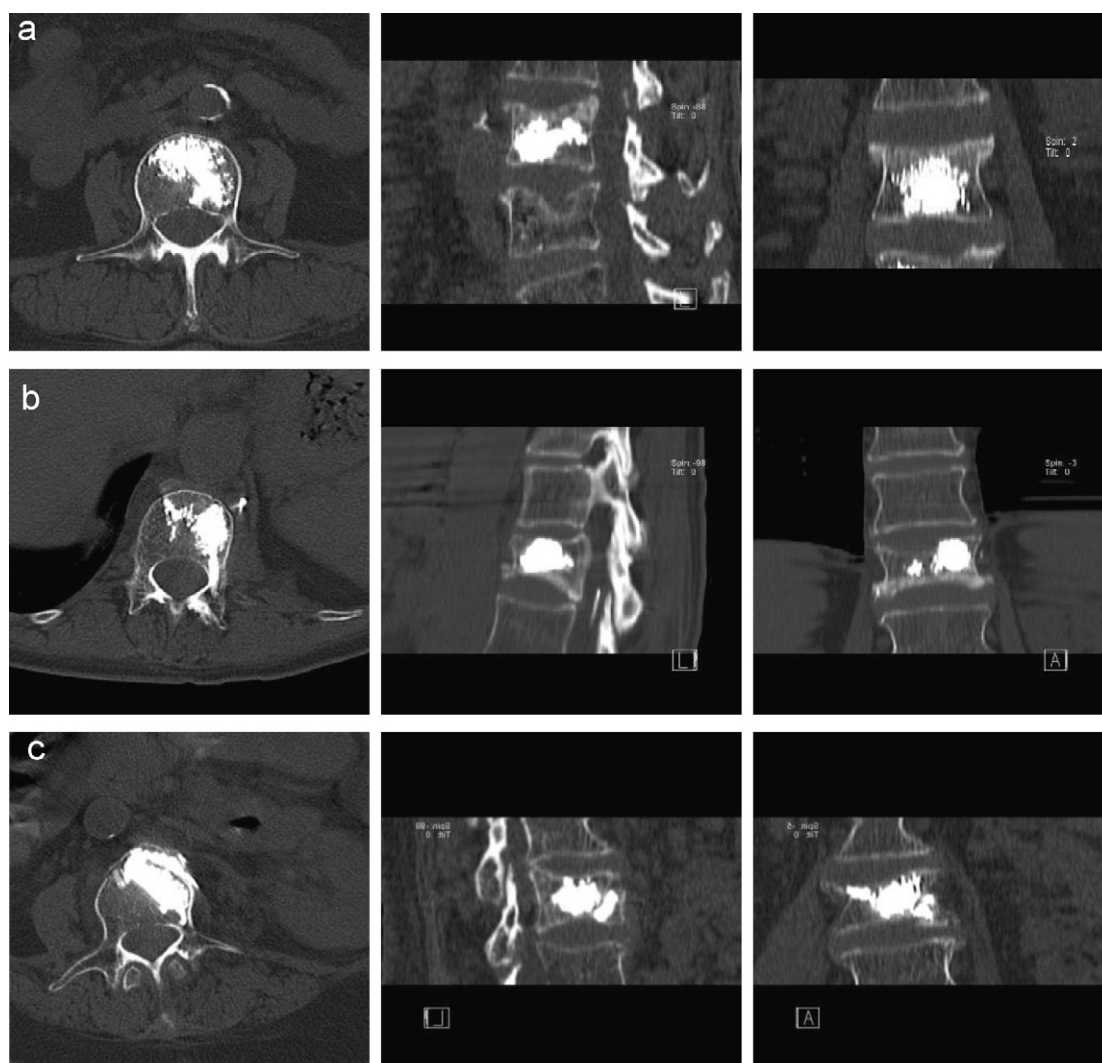


Figure 3 Example of cement distribution, visualized by computed tomography: a) vertebroplasty; b) balloon kyphoplasty, and c) shield kyphoplasty.

quality of life on the ODI, at a mean 6 months post-surgery. The secondary objective was to analyze current radiological imaging (X-ray and, in some cases, CT) with regard to height restoration, cement distribution and leakage and new fracture. On the 100-point VAS, patients in the balloon kyphoplasty group indicated a mean 53.5 point reduction in pain, compared to a mean reduction of 45.6 points in the vertebroplasty group and of 48 points in the shield kyphoplasty group. Improvements on the ODI were less pronounced: a significant improvement of 22% to 45% was found overall but, as with the VAS scores, there was no significant difference between the three augmentation procedures.

As previous studies found no correlation between reconstruction of the vertebral body and clinical outcome (pain reduction) [5,6], this analysis was intentionally abandoned. In the present series, no significant increase in vertebral body height was noted, as shown by the unchanged Beck index. This was expected for vertebroplasty and shield kyphoplasty, where anterior column reconstruction is achieved by ligamentotaxis due to the position of the patient. The lack of height restoration by balloon

kyphoplasty was probably an effect of the unilateral procedure, or the small sample size. The mean interval of more than 4 weeks between trauma and surgery may also explain the limited reduction. Nevertheless, all patients resumed normal daily activities after the procedure.

Pain scores improved significantly. The immediate clinical benefit of cement augmentation in osteoporotic patients with chronically painful vertebral fracture does not appear to depend on a morphological correction of the fractured vertebra. This was also shown by the unchanged Beck index [3].

Even if no lateral wedging, curve deterioration or new scoliotic curve occurred during the 6 months' follow-up, this complication should be kept in mind when using a unilateral approach, especially in balloon kyphoplasty, where a cavity is created. If the needle position is sub-optimal (e.g., too lateral) this could induce lateral wedging and affect long-term coronal alignment. In 42 patients identified as having preoperative coronal deformity, no curve deterioration or new scoliotic curve was found on last radiographic assessment.

Table 3 Results for visual analog scale, Oswestry Disability Index and Oswestry Disability Index improvement.

Technique	VAS preoperative (mean)	VAS postoperative (mean)	ODI preoperative (mean)	ODI postoperative (mean)	ODI improvement
Kyphoplasty (n = 20)	90 (SD: 7.07)	36.5 (SD: 6.36)	77 (SD: 4.2)	43.1 (SD: 19.5)	45%
Vertebroplasty (n = 21)	78.2 (SD: 9.36)	32.4 (SD: 14.04)	68.2 (SD: 5.7)	53.1 (SD: 8.5)	22%
Shield kyphoplasty (n = 18)	88.16 (SD: 15.06)	40.16 (SD: 7.44)	75.7 (SD: 9.1)	56.1 (SD: 7.6)	24%

VAS: visual analog scale; ODI: Oswestry Disability Index.

The main focus was rather on risk related to cement distribution, cement leakage and surgery time with respect to dose-area product ($\text{cGy} \times \text{cm}^2$). The rate of cement leakage was 36% for vertebroplasty, 13% for balloon kyphoplasty and 4% for shield kyphoplasty. This is roughly in agreement with reports in the current literature, in which leakage is reported to reach 88% for vertebroplasty [5,7] and 33% for balloon kyphoplasty [2,8–11]; no published data are available for shield kyphoplasty. Balloon kyphoplasty leakage rates are slightly higher in the present study than the 9% reported for all bipedicular kyphoplasties in Hulme et al.'s literature review [8], probably due to small sample size. However, this was unrelated to the unilateral approach: cement will pursue the path of least resistance through fracture lines or the vertebral venal plexus, independently of the cannulation procedure, whether unilateral or bilateral.

In our opinion, a potentially decisive difference in favor of shield kyphoplasty and vertebroplasty lay in the distribution of the cement in the vertebral body, which could possibly affect the rate of new fracture. In comparison, balloon kyphoplasty has the disadvantage of unsatisfactory cement distribution in the vertebral body, presumably due to the formation of a cavity by the balloon, with packing of the spongy structures, so that the flow of cement into the remaining vertebral body parts is prevented.

With regard to surgery time, fluoroscopy time and dose-area-product, there were significant differences obviously favoring the vertebroplasty technique. Concerning the main objective of the study, clinical outcome, however, no significant difference between the three techniques was seen overall.

Conclusions

This is probably the first study to compare clinical outcome for different cement augmentation systems performed through a unipedicular approach. It provides evidence that the kind of cement augmentation system used for primary osteoporosis patients suffering from chronically painful osteoporotic vertebral fracture does not matter, especially in terms of pain relief.

The unilateral Soteira technique was comparable to unilateral balloon kyphoplasty regarding leakage and surgery time, was better than unilateral vertebroplasty regarding leakage, and gave the same pain relief as the other two techniques.

Overall, setting aside the mostly asymptomatic leakage of cement, the vertebroplasty technique may be considered the surgical procedure of choice.

Disclosure of interest

The author declares that he has no conflicts of interest concerning this article.

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